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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,853	09/16/2003	Pranhitha Reddy	3226-A	2860

7590 07/14/2004

Immunex Corporation
Law Department
51 University Street
Seattle, WA 98101

EXAMINER
DESAI, ANAND U

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,853	REDDY ET AL.	
	Examiner	Art Unit	
	Anand U Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *24, 25, 27, and 29* is/are allowed.

6)☒ Claim(s) *1,3,4,7-12,14-18,22,23,26 and 28* is/are rejected.

7)☒ Claim(s) *1, 2, 5, 6, 13, 19, 20, and 21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *May 7, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(e). The priority date is September 20, 2002.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on May 7, 2004 is being considered by the examiner.

Specification

3. The disclosure is objected to because of the following informalities:

4. There are typographical errors on pages 6-8; the figures for deoxycytidine do not have a NH_2 group on the C4 position of the purine ring.

Appropriate correction is required.

Claim Objections

5. Claim 1 is objected to because of the following informalities: The cell culture Chinese hamster ovary should be written out prior to the first occurrence of an abbreviation, CHO.

Appropriate correction is required.

6. Claims 2, 5, 6, 13, 19, 20, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 26, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 26, and 28 claim a mammalian cell culture, but it appears to be drawn to CHO cells in particular? The indefiniteness would be overcome by replacing the word "mammalian" with "CHO".

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 9, 10, 12, 14, 15, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanigawa et al. (Journal of Fermentation and Bioengineering, Vol. 75, No. 4, pp. 254-258 (1993)). Tanigawa et al. discloses the enhancement of expression of an introduced gene by 5-azacytidine in a Chinese hamster ovary cell line, CHO-K1. Tanigawa et al. produced stable transformants of CHO-K1 cells containing a pCDSRα287 plasmid, which contains the human interleukin 2 gene (IL-2). The IL-2 gene is under the control of the SRα promoter that is composed of the SV40 early promoter and the R-U5 sequence of the long terminal repeat of T-cell leukemia virus type 1 (see pp. 257 section on Specificity of the effect of 5-azaC, 3rd

paragraph). The concentration of 5-azacytidine varied from 0 to 10 μM. The concentration of IL-2 produced was measured from culture supernatants (see pp. 258, Figure 7; current application, claims 1, 9, 10, 12, 14, 15, and 22).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 3, 4, 7, 9, 10, 12, 14, 15-18, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanigawa et al. (Journal of Fermentation and Bioengineering, Vol. 75, No. 4, pp. 254-258 (1993)). Tanigawa et al. discloses the enhancement of expression of an introduced gene by 5-azacytidine in a Chinese hamster ovary cell line, CHO-K1. Tanigawa et al. produced stable transformants of CHO-K1 cells containing a pCDSRα287 plasmid, which

contains the human interleukin 2 gene (IL-2). The IL-2 gene is under the control of the SRα promoter that is composed of the SV40 early promoter and the R-U5 sequence of the long terminal repeat of T-cell leukemia virus type 1 (see pp. 257 section on Specificity of the effect of 5-azaC, 3rd paragraph). The concentration of 5-azacytidine varied from 0 to 10 μM. The concentration of IL-2 produced was measured from culture supernatants (see pp. 258, Figure 7). Both 5-azacytidine and 5-aza-2'-deoxycytidine cause DNA demethylation or hemi-demethylation. Therefore, it would have been obvious to a person having ordinary skill in the art to substitute 5-aza-2'-deoxycytidine for 5-azacytidine (current application, claims 1, 3, 4, 7, 9, 10, 12, 14, 15-18, and 22).

14. Claims 1, 3, 4, 7-12, 14-18, 22, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanigawa et al. (Journal of Fermentation and Bioengineering, Vol. 75, No. 4, pp. 254-258 (1993)) in view of Lucas et al. (Nucleic Acids Research Vol. 24, No. 9 pp. 1774-1779 (1996)). Tanigawa et al. discloses the enhancement of expression of an introduced gene by 5-azacytidine in a Chinese hamster ovary cell line, CHO-K1. Tanigawa et al. produced stable transformants of CHO-K1 cells containing a pCDSRα287 plasmid, which contains the human interleukin 2 gene (IL-2). The IL-2 gene is under the control of the SRα promoter that is composed of the SV40 early promoter and the R-U5 sequence of the long terminal repeat of T-cell leukemia virus type 1 (see pp. 257 section on Specificity of the effect of 5-azaC, 3rd paragraph). The concentration of 5-azacytidine varied from 0 to 10 μM. The concentration of IL-2 produced was measured from culture supernatants (see pp. 258, Figure 7). Both 5-azacytidine and 5-aza-2'-deoxycytidine cause DNA demethylation or hemi-demethylation.

Lucas et al. describes the recombinant production of humanized antibodies directed against IgE. The anti-IgE antibody was produced from a SV40 driven vector (see Lucas, B. et al. Nucleic Acids Research, particularly pp. 1776 Results section, Production of antibodies using the DI vector). Lucas, B. et al. also discuss the production of non-productive clones that could be due to the silencing of promoters by methylation (see pp. 1778, Discussion, 2nd paragraph). Therefore, it would have been obvious to a person having ordinary skill in the art to uses 5-aza-2'-deoxycytidine to active silenced promoters in CHO cells which are producing recombinant antibodies (current application, claims 1, 3, 4, 7-12, 14-18, 22, 23).

Allowable Subject Matter

15. Claims 24, 25, 27, and 29 are allowable.

Conclusion

16. Claims 1, 2, 5, 6, 13, 19, 20, and 21 are objected.

17. Claims 1, 3, 4, 7-12, 14-18, 22, 23, 26, and 28 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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July 6, 2004

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER